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Pharmacovigilance: Concept, Procedure and Information resources

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ABSTRACT:-
Pharmacovigilance is the science and practice dedicated to monitoring, evaluating, and improving the safety of pharmaceutical products. It encompasses the detection, assessment, understanding, and prevention of adverse effects or any other drug-related issues. The concept of pharmacovigilance extends beyond the management of adverse drug reactions (ADRs) to include medication errors, misuse, abuse, and drug exposure during sensitive periods like pregnancy and breastfeeding. The pharmacovigilance procedure involves systematic collection, evaluation, and reporting of safety data from various sources, including clinical trials, post-marketing surveillance, healthcare professionals, and patients. Regulatory authorities such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) have established frameworks to guide these processes. Key information resources supporting pharmacovigilance activities include spontaneous reporting databases, electronic health records, scientific literature, and risk management plans. Together, these components ensure that medicines remain safe and effective throughout their lifecycle, reinforcing public trust in therapeutic interventions.
Keywords: Pharmacovigilance, ADRs, concept, ADR reporting, clinical trials, post marketing surveillance.

I. INTRODUCTION:-

Pharmacovigilance (PV) is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects (AEs) or any other drug-related problems associated with pharmaceutical products. It is a critical component of drug safety and public health, ensuring that medicines are used safely and effectively.

The term "pharmacovigilance" has its roots in two ancient words: "pharmakon," which is Greek for "drug," and "vigilare," a Latin word meaning "to keep watch." Together, these words capture the essence of pharmacovigilance keeping a close eye on drugs to ensure their safety. At its core, pharmacovigilance is deeply concerned with adverse drug reactions (ADRs), which are defined as any harmful or unintended response to a medication. This definition also covers situations where a drug fails to work as intended, such as a lack of efficacy. In other words, if a drug doesn't produce the desired effect at the doses normally used for prevention, diagnosis, or treatment of a disease or, in the case of medical devices, for modifying physiological functions it falls under the scope of pharmacovigilance.[1]

Over time, the scope of pharmacovigilance has expanded. In 2010, the European Union broadened its focus to include medication errors, such as overdoses, misuse, and abuse of drugs, as well as drug exposure during pregnancy and breastfeeding. These situations are monitored even if no adverse event has occurred, as they have the potential to lead to harm. Similarly, the U.S. Food and Drug Administration (U.S. FDA) has long considered these criteria to be part of reportable and collectible pharmacovigilance standards. This evolution reflects the growing understanding that drug safety isn't just about reacting to harm it's also about proactively identifying and preventing risks before they cause damage.

The objective of pharmacovigilance is to ensure the safety, efficacy, and quality of medicines by identifying, assessing, understanding, and preventing adverse effects or any other drug-related problems. [1, 2]

Aims of Pharmacovigilance:-

The primary objectives of pharmacovigilance for human medicines can be readily adapted for veterinary use as well. These aims include:

- Detecting and measuring adverse drug reactions (ADRs) that were previously unrecognized.
- Identifying specific groups of patients that may be at greater risk of ADRs, considering factors such as species, breed, age, gender,

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physiological state, and existing health conditions.
- Ongoing surveillance of a product's safety across all species for which it has been approved, ensuring that the benefit-risk balance remains favorable. This should also cover monitoring for newly approved indications or species.
- Evaluating the adverse event profiles of products within the same therapeutic category, both within individual species and across different species.
- Identifying inappropriate prescribing practices and incorrect methods of drug administration, particularly when administration is carried out by individuals such as farmers or the general public.
- Conducting further research into a drug's toxicological, pharmacological, or microbiological properties to better understand the mechanisms behind adverse reactions.
- Monitoring for interactions between different drugs, which is especially important when newly introduced medications are used alongside existing or other new products.
- Providing accurate and timely information on ADRs and drug interactions to veterinarians and others involved in animal care, such as farmers and animal owners.
- Observing and assessing the impact of veterinary medicines on the environment and organisms living within it.
- Monitoring violations of permissible residue levels of veterinary drugs in food products derived from animals, such as meat, milk, and honey.[1,2]

Historical Background of Pharmacovigilance:-

Pharmacovigilance, the science and activities related to detecting, assessing, understanding, and preventing adverse effects or any other drug-related problems, has evolved over centuries. The discipline emerged in response to various medical tragedies and has since developed into a structured global system. Below is a detailed historical background of pharmacovigilance. [5,9]

1. Ancient and Pre-Modern Drug Safety Measures

- **Ancient Egypt, Greece, and Rome:** The Ebers Papyrus (c. 1550 BCE) documented numerous medicinal preparations and warnings about toxic substances. Similarly, Hippocrates (460–370 BCE) emphasized the importance of observing and recording drug effects. Dioscorides (1st century CE) cataloged herbal remedies and their potential toxic effects.
- **Middle Ages:** Herbal medicine was widely practiced, with knowledge passed orally or through manuscripts. However, systematic drug monitoring was absent.[5]

2. The 19th Century: Foundations of Drug Safety Awareness

- **1848 – The First Recorded Drug Safety Concern:** The first known drug safety issue was recorded in the United States after the death of a young girl who consumed an adulterated chloroform-containing medicine. This incident led to the first piece of drug safety legislation—the Drug Importation Act of 1848.
- **Development of Modern Pharmacology:** Scientists such as François Magendie and Claude Bernard advanced knowledge of drug mechanisms, laying the foundation for rational therapeutics.[4]

3. Early 20th Century: Regulatory Beginnings

- **1906 – The U.S. Pure Food and Drug Act:** This act marked the first federal law in the United States regulating drugs, aiming to prevent misbranding and adulteration.
- **1937 – The Sulfanilamide Disaster:** Over 100 people died in the U.S. after consuming sulfanilamide elixir formulated with diethylene glycol, a toxic solvent. This led to the **1938 Federal Food, Drug, and Cosmetic Act**, requiring drug manufacturers to prove the safety of their products before marketing.[11]

4. The 1960s: The Birth of Modern Pharmacovigilance

The most significant event leading to modern pharmacovigilance was the **thalidomide disaster** of the late 1950s and early 1960s.

- **Thalidomide Tragedy (1957–1961):** Thalidomide, a drug marketed for morning sickness, caused severe birth defects (phocomelia) in thousands of babies worldwide.
- **Regulatory Response:**
  - The **1962 Kefauver-Harris Amendment (USA)** mandated rigorous drug safety and efficacy testing before approval.
  - The **Committee on the Safety of Drugs (UK)** was formed in 1963 to monitor drug safety.

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- The **World Health Organization (WHO) established the Programme for International Drug Monitoring (PIDM) in 1968**, creating the foundation for global pharmacovigilance.[3,4]

5. Expansion of Global Pharmacovigilance (1970s–1990s)

- **1970s:** Many countries established their own national pharmacovigilance centers.
- **1978 – WHO's Uppsala Monitoring Centre (UMC):** The UMC in Sweden became the global hub for pharmacovigilance, collecting and analyzing adverse drug reaction (ADR) reports.
- **1980s–1990s:** The concept of **risk-benefit analysis** and **post-marketing surveillance** became central to drug regulation.[7]

6. 21st Century: Strengthening Pharmacovigilance

- **2001 – European Medicines Agency (EMA) Expands Pharmacovigilance:** The European Union introduced stricter pharmacovigilance regulations after drug safety concerns.
- **2010s – Strengthening of Pharmacovigilance in Developing Countries:** Many developing nations established regulatory agencies and ADR reporting systems.
- **2012 – The EU Pharmacovigilance Legislation:** The EU passed the Pharmacovigilance Directive (2010/84/EU) and Regulation (1235/2010), further strengthening drug safety monitoring.[8]

7. Present and Future Trends

- **Big Data & Artificial Intelligence in Pharmacovigilance:** AI and machine learning are being increasingly used to detect ADRs from large datasets.
- **Patient-Centric Pharmacovigilance:** Patients are now encouraged to report ADRs directly.
- **Pharmacovigilance in Biologics & Gene Therapies:** With the rise of biologics and personalized medicine, new safety monitoring strategies are being developed.[8,14]

Key milestone

Year	Events
1820	Establishment of the U.S. Pharmacopeia (USP).
1906	U.S. Pure Food and Drug Act.
1937	Sulfanilamide disaster leads to the 1938 Federal Food, Drug, and Cosmetic Act.
1961	Thalidomide tragedy.
1968	WHO launches the International Drug Monitoring Programme.
1990	Establishment of the ICH.
1993	FDA launches the MedWatch program.
2010	EU Pharmacovigilance Legislation expands the scope of pharmacovigilance.
2012	EU establishes the Pharmacovigilance Risk Assessment Committee (PRAC).
2020s	Focus on real-world evidence, AI, and global collaboration.

Table: 1.1

Concept of pharmacovigilance

According to the World Health Organization (WHO), an adverse drug reaction (ADR) is described as a harmful and unintended response to a medication that occurs when it is administered at normal doses intended for prevention, diagnosis, treatment of disease, or for altering physiological functions. ADRs are a frequent clinical issue and contribute significantly to both illness and death. Pharmacovigilance is

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defined as the scientific discipline and set of activities focused on identifying, evaluating, understanding, and preventing adverse effects or any other problems related to drug use.[23]

Definition and scope:-

1. Adverse Drug Reactions (ADRs) and Adverse Events (AEs)

- **Adverse Drug Reaction (ADR):** A harmful and unintended response to a drug when used at normal doses.
- **Example:** Liver damage caused by excessive use of **paracetamol**.
- **Adverse Event (AE):** Any unwanted event that occurs after taking a drug but is not necessarily related to it.
- **Example:** A patient taking antibiotics develops a headache, but the cause is unclear.[18]

Types of ADRs:-

- **Type-A (Augmented):** Predictable reactions based on drug mechanism. (e.g. **hypoglycemia** from insulin).
- **Type-B (Bizarre):** Unpredictable, immune-mediated reactions (e.g. **anaphylaxis** to penicillin).
- **Type-C (Chronic):** Due to long-term drug use (e.g. kidney damage from **NSAIDs**).
- **Type-D (Delayed):** Appears after long-term use (e.g. cancer from chemotherapy drugs).
- **Type-E (End-of-use):** Occurs after suddenly stopping a drug (e.g. withdrawal symptoms from **opioids**).
- **Type-F (Failure):** Drug does not work as expected (e.g. **antibiotic resistance**).[18,19]

Drug interactions:-

A drug interaction occurs when one drug affects the action of another drug, leading to enhanced, reduced, or unexpected effects. This can happen when two or more medications are taken together, or when drugs interact with food, alcohol, or medical conditions.

Drug interactions can be beneficial, harmful, or neutral depending on the situation.[20,21]

Types of Drug Interactions:-

(A) Drug-Drug Interactions (DDIs)

- Occurs when two or more drugs interact, affecting their effectiveness or safety.

(a) Synergistic Effect (Additive or Potentiating Interaction)

- **Examples:** Alcohol + Sedatives (e.g., Benzodiazepines) → Excessive sedation or respiratory depression.

(b) Antagonistic Effect: One drug reduces or blocks the effect of another.

- **Example:** Beta-blockers + Beta-agonists (e.g., Propranolol + Albuterol) → Reduced effectiveness of asthma treatment.

(B) Drug-Food Interactions

- Occurs when food affects the absorption, distribution, metabolism, or elimination of a drug.

Example:

- Grapefruit juice + Statins (e.g., Atorvastatin, Simvastatin) → Increases drug levels, leading to toxicity.
- Leafy greens (high in Vitamin K) + Warfarin → Decreases anticoagulant effect, increasing clot risk.

(C) Drug-Disease Interactions

- Occurs when a drug worsens an existing medical condition.

Example:

- Beta-blockers (e.g., Propranolol) in Asthma Patients → can trigger asthma attacks.
- NSAIDs (e.g., Ibuprofen) in Hypertension or Kidney Disease → can increase blood pressure and cause kidney damage.[21]

How to Prevent Drug Interactions:-

a) Check Medication Labels and Warnings – Look for potential interactions before taking a new drug.

b) Use a Single Pharmacy– Pharmacists can monitor for dangerous combinations.

c) Informs Your Doctor about All Medications – Include prescription drugs, OTC medicines, herbal supplements, and vitamins.

d) Avoid Alcohol When Taking Medications – It can interfere with many drugs.

e) Monitor for Symptoms of Drug Interactions – Watch for unusual side effects like dizziness, drowsiness, nausea, or excessive bleeding.

f) Use Drug Interaction Tools – Websites and mobile apps (e.g., Medscape, Drugs.com) can check for interactions.[20]

Procedure in Pharmacovigilance

The primary goal of pharmacovigilance is to ensure the safety, efficacy, and quality of medicines by continuously monitoring and evaluating their risk-benefit balance. Regulatory

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agencies such as the U.S. FDA, EMA (European Medicines Agency), WHO (World Health Organization), and CDSCO (India's regulatory body) oversee pharmacovigilance systems worldwide.

The pharmacovigilance process consists of a series of well-defined procedures to collect, assess, and act upon drug safety data.[24,25]

Adverse Event (AE) Reporting

Adverse events (AEs) refer to any **undesirable experience** associated with the use of a medical product. Reporting AEs is a critical step in pharmacovigilance, enabling regulatory bodies to monitor drug safety.

To monitor and manage ADRs effectively, a reporting system is essential. An ADR Reporting System is a structured mechanism for collecting, analyzing, evaluating, and responding to adverse reactions associated with pharmaceutical products.[21,27]

Sources of Adverse Event Reports:-

- **Healthcare professionals** (doctors, nurses, pharmacists).
- **Patients and consumers** (through help lines, online forms, or direct reporting systems).
- **Pharmaceutical companies** (obliged to report any AE related to their products),
- **Regulatory authorities** (data collected through national and international monitoring systems).
- **Medical literature and clinical studies** (published case reports, trials).

Types of Reporting:

- **Spontaneous Reporting Systems (SRS)**: Voluntary reports submitted to national or international databases.
- **Solicited Reports**: Data collected through organized data collection systems like patient support programs or market research programs.
- **Clinical Trials Reporting**: Especially during Phases I–IV, where adverse events are strictly monitored and reported.

(a) Spontaneous reporting system

A Spontaneous Reporting System is a passive surveillance mechanism where healthcare professionals (and sometimes patients) voluntarily report Adverse Drug Reactions (ADRs) to a national or regional pharmacovigilance centre. [26]

Feature	Description
Voluntary Reporting	Reports are submitted without active solicitation.
Suspected ADRs	Focuses on suspected (not necessarily proven) adverse reactions.
Real-World Data	Collects information from clinical practice rather than clinical trials.
Signal Detection	Helps identify previously unknown risks (new side effects, drug interactions).

Table: 1.2

(b) Solicited reports:-

A solicited report is an adverse event (AE) report that comes from organized data collection systems, such as:

- Clinical trials.
- Post-authorization safety studies (PASS).
- Patient support programs.
- Disease management programs.
- Registries.

(c) Clinical trials reporting:-

Clinical trials reporting in pharmacovigilance involves the collection, evaluation, and submission of safety data (i.e., adverse events) that occur during clinical trials—from Phase I to Phase IV. This type of reporting is a form of **solicited reporting** because it's part of a structured and regulated data collection process.[22]

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Term	Meaning
AE (Adverse Event)	Any untoward medical occurrence in a patient during a clinical trial, not necessarily causally related to the drug.
ADR (Adverse Drug Reaction)	A noxious and unintended response to a drug, where a causal relationship is suspected.
SAE (Serious Adverse Event)	An AE that results in death, life-threatening situation, hospitalization, disability, congenital anomaly, or requires intervention.

Table: 1.3

ADR reporting system

An Adverse Drug Reaction (ADR) is defined by the World Health Organization (WHO) as "a response to a drug that is noxious and unintended and occurs at doses normally used in humans for prophylaxis, diagnosis, therapy, or modification of physiological function."

To monitor and manage ADRs effectively, a reporting system is essential. An ADR Reporting System is a structured mechanism for collecting, analyzing, evaluating, and responding to adverse reactions associated with pharmaceutical products.[27,28]

Types of ADR Reporting Systems:-

(a) Spontaneous Reporting Systems (SRS)

- Voluntary or mandatory submission of ADR reports by healthcare professionals, patients, or pharmaceutical companies.
- Most common and foundational form of ADR surveillance.

(b) Intensive Monitoring

- Used in hospitals or specific clinics.
- Trained professionals closely observe patients for ADRs during treatment.

(c) Electronic Reporting Systems

- Integrated with Electronic Health Records (EHRs)**.**
- Real-time reporting through digital platforms.

(d) Active Surveillance Programs

- Patients are systematically followed after receiving a medication.
- Includes prescription event monitoring, cohort studies, registries.

(e) Who Can Report ADRs?

- Healthcare professionals**:** doctors, nurses, pharmacists, dentists.
- Pharmaceutical companies**:** as a regulatory requirement.
- Patients and caregivers**:** increasingly encouraged.
- Regulatory authorities: can receive, evaluate, and forward reports.

(f) An ADR report typically includes:

- **Patient information** (age, gender, medical history).
- **Details of the suspected drug** (name, dosage, duration).
- **Description of the reaction** (onset, severity, outcome).
- **Concomitant medications**.
- **Reporter's information** (optional if anonymous reporting is allowed).

Objectives of ADR Reporting Systems

- Early detection of new, rare, or serious adverse drug reactions.
- Monitor trends and incidence of known adverse reactions.
- Identify risk factors or patient groups at higher risk.
- Promote safer drug use.
- Support regulatory decisions such as label updates, usage restrictions, or drug withdrawals.[27,29]

Post-Marketing Surveillance

Post-Marketing Surveillance (PMS) is a crucial aspect of pharmacovigilance that involves the continuous monitoring of a drug's safety after it has been approved and made available to the public. The main objective is to detect, assess, and prevent adverse drug reactions (ADRs) and ensure that the benefit-risk profile of the drug remains favourable throughout its market life.[25]

Objectives of Post-Marketing Surveillance

- Identify rare, delayed, or long-term adverse drug reactions.
- Monitor drug performance in real-world settings.

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- Ensure safe use of the drug in special populations (e.g., elderly, pregnant women, children).
- Detect drug interactions or misuse.
- Support regulatory actions like labelling changes, warnings, or market withdrawal.[24,25]

Phase-4 studies:-

Phase 4 clinical trials, also known as post-marketing studies**,** are conducted after a drug has been approved for public use by regulatory agencies such as the FDA (USA), EMA (EU), or CDSCO (India). Unlike the earlier phases (I–III), which focus on safety, efficacy, and dosage, Phase 4 trials focus on long-term safety, effectiveness in real-world settings, and rare or delayed adverse drug reactions (ADRs).[29]

Types of Phase 4 Studies:

(a) Observational Studies

- **Cohort Studies**: Follow a group of patients taking the drug and monitor outcomes over time.
- **Case-Control Studies**: Compare patients with a specific ADR (cases) to those without (controls).
- **Cross-sectional Surveys**: Collect data at a single point in time to evaluate usage patterns or side effects.

(b) Interventional Studies

- Randomized controlled trials conducted post-approval to assess specific safety or efficacy questions.
- May compare the approved drug to another therapy or placebo.

(c) Registry Studies

- Collect long-term data on patients with a particular disease or on a specific drug.
- Useful in special populations (e.g., cancer patients, pediatric, geriatric).

(d) Regulatory Importance of Phase 4 Trials

- **FDA (USA)** can mandate Phase 4 studies as part of a REMS program.
- EMA (Europe) may require Phase 4 under a Risk Management Plan (RMP).
- Non-compliance with required post-marketing studies can lead to:
  - Withdrawal of drug approval.
  - Fines or legal actions.

Benefits of Phase 4 Trials in Pharmacovigilance

- Detect rare adverse drug reactions not seen in earlier phases.
- Evaluate safety in populations not studied previously (e.g., patients with comorbidities).
- Understand drug interactions with commonly used medications.
- Support safe and rational use of medications through real-world evidence.
- Provide data for health policy and reimbursement decisions.[28,29]

Information resources in pharmacovigilance

In pharmacovigilance, information resources are essential for collecting, evaluating, and acting on safety data related to medicinal products. These resources are broadly categorized based on the type and source of information they provide.

Information resources in pharmacovigilance refer to the various sources and tools used to collect, assess, monitor, and analyze data related to the safety and adverse effects of pharmaceutical products.[30,31]

These resources are essential for:

- Detecting new or rare adverse drug reactions (ADRs).
- Evaluating the risks and benefits of medicines.
- Supporting regulatory decisions.
- Ensuring patient safety.

1. Regulatory Authority Databases

These are government or intergovernmental bodies responsible for the safety and regulation of medicines.

(a) WHO-Uppsala Monitoring Centre (UMC) – VigiBase

- **What it is**: The global database of individual case safety reports (ICSRs).
- **Managed by**: WHO and UMC (Sweden).
- **Use**: Global signal detection, adverse event reporting trends.[12]

(b) US FDA – FAERS (FDA Adverse Event Reporting System)

- **What it is**: US-based system for post-marketing safety surveillance.
- **Use**: Monitoring of adverse event reports submitted to the FDA.[6,7]

(c) EMA – EudraVigilance

- **What it is**: European database for managing and analyzing information on suspected adverse reactions.
- **Managed by**: European Medicines Agency.
- **Use**: Signal detection and risk assessment in the EU.

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(d) MHRA – Yellow Card Scheme (UK)
- **What it is**: UK's spontaneous reporting system for adverse drug reactions.
- **Use**: Monitoring the safety of medicines and medical devices.[32]

2. Medical and Scientific Literature

Literature is a primary source of safety data, especially for signal detection.
- **PubMed / MEDLINE**
- **Use**: Access to biomedical and life sciences journal articles.
- **Search for**: Case reports, reviews on drug safety.
- **EMBASE**
- **Use**: European equivalent of MEDLINE with broader pharmacovigilance content.
- **Advantage**: Includes more European journals and conference abstracts.
- **Science Direct / Springer / Wiley Online Library**
- **Use**: Comprehensive databases for drug safety articles and studies.

3. Spontaneous Reporting Systems (SRS)

These are databases where healthcare professionals, patients, and manufacturers report adverse drug reactions (ADRs).
- **Examples**:
- **FAERS** (US FDA Adverse Event Reporting System)
- **EudraVigilance** (European Medicines Agency)
- **VigiBase** (WHO global database)
- **Yellow Card Scheme** (UK MHRA)
- **Use**: Signal detection, trend analysis, regulatory actions.[26]

4. Clinical Trial Data

Pre- and post-marketing clinical trials provide structured safety data.
- **Sources**:
- Clinical trial registries (e.g., ClinicalTrials.gov).
- Study reports submitted to regulators.
- Sponsor trial databases.
- **Use**: Identifying expected ADRs, evaluating drug safety before and after approval.[14]

5. Pharmacovigilance Databases and Software

Used by pharmaceutical companies and regulators for managing safety data.
- **Examples**:
- Oracle Argus Safety
- ARISg
- VigiLyze (UMC)
- Empirical Signal
- **Use**: Case processing, signal detection, risk evaluation, and reporting.[12]

6. Internal Company Data

Pharmaceutical companies collect proprietary data from:
- Post-marketing surveillance
- Periodic Safety Update Reports (PSURs)
- Risk Management Plans (RMPs)
- Literature monitoring teams
- **Use**: Internal signal tracking, compliance reporting, and decision-making.[26,30]

7. Social Media and Digital Platforms (Emerging Resource)

Patients may report adverse effects or experiences with drugs on platforms like:
- Twitter, Facebook, health forums (e.g., Reddit, PatientsLikeMe)
- Mobile health apps and software.
- **Use**: Early signal detection and understanding patient perspectives (still under regulatory evaluation).[33]

Future Prospects:-

As the scope of pharmacovigilance (PV) expands, there is a growing need for systems capable of detecting new adverse drug reactions (ADRs) and initiating appropriate regulatory measures to safeguard public health. However, relatively little attention has been given to producing information that can support healthcare professionals and patients in making informed decisions. Collecting and effectively communicating this information is a crucial objective of pharmacovigilance.[34]

Reliable safety data from active surveillance efforts are essential. When designing new strategies for active post-marketing surveillance, it is important to prioritize the collection of comprehensive and accurate data, especially concerning serious adverse events. While spontaneous reporting is valuable for generating early safety signals, the limited volume of reports for specific drug-event combinations makes it less effective in identifying patient-specific risk factors.[34,35]

Therefore, PV methods must evolve to identify which patient groups are at greater risk of experiencing ADRs. Pharmacovigilance, as a source of vital safety information, aligns well with

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the increasing involvement of patients in their own healthcare. In the future, PV systems should not only focus on traditional sources like healthcare professionals but also include patients as key contributors of safety data.

In India, the Drug Controller General of India (DCGI) should take immediate steps to enhance PV practices by integrating Good Pharmacovigilance Practices (GPP) into standard procedures. This will ensure better regulatory compliance, improve clinical trial oversight, and strengthen post-marketing surveillance. A well-functioning PV system is critical for ensuring the safe use of medicines. It benefits all stakeholders' healthcare providers, regulatory bodies, pharmaceutical companies, and most importantly, patients. For pharmaceutical companies, PV helps monitor the safety profile of their products and manage associated risks effectively.[35,36]

II. CONCLUSION:-

Pharmacovigilance stands as a cornerstone of modern medicine and public health, providing a systematic framework for ensuring that pharmaceutical products are not only effective but also safe for widespread use. By continuously monitoring adverse effects, drug inefficacies, and potential risks, pharmacovigilance bridges the gap between clinical trials and real-world drug use, where broader and more diverse populations may reveal safety concerns not previously identified.[36]

While the field initially centered on detecting and analyzing adverse drug reactions (ADRs), its scope has expanded significantly. Modern pharmacovigilance now includes the identification and prevention of medication errors, misuse, abuse, overdose, and exposure during sensitive periods like pregnancy and lactation even when no immediate harm is observed. This proactive shift in focus highlights a paradigm change: from simply responding to negative outcomes to anticipating and mitigating risks before they materialize.

The global alignment of pharmacovigilance practices, as seen in the frameworks developed by the European Union, the U.S. FDA, and the World Health Organization, underscores its universal importance in drug regulation and public health. These evolving standards emphasize not only regulatory compliance but also ethical responsibility toward patients and healthcare systems.

In essence, pharmacovigilance ensures that the benefits of a medicine always outweigh its risks. It is a dynamic and evolving discipline that supports informed decision-making by healthcare professionals, regulators, and pharmaceutical companies. Through vigilant observation, timely reporting, and continuous assessment, pharmacovigilance helps protect patients, foster safe therapeutic environments, and sustain public trust in medical treatments.[36,37]

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